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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: O. S. Khalil, et al.

Serial No: 09/419,461

Filed: October 15, 1999

For: METHOD FOR MODULATING LIGHT PENETRATION DEPTH IN TISSUE AND DIAGNOSTIC APPLICATIONS USING SAME

Group Art Unit: 3736

Examiner: M. Kremer

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Michele M. Bonke

BRIEF ON APPEAL

Assistant Commissioner for Patents
Washington, D.C. 20231

Attention: Board of Patent Appeals and Interferences

Dear Sir:

This brief is in furtherance of the Notice of Appeal filed in this application on March 19, 2002, as evidenced by the "Office Date" Stamp.

The fees required under 1.17(c) and any required petition for extension of time for filing this brief and fees therefor are dealt with in the accompanying TRANSMITTAL OF BRIEF ON APPEAL. This brief is being submitted in triplicate. This brief contains these items under the following headings and in the order set forth below:

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of the Invention
VI. Issues

I. REAL PARTY IN INTEREST

The real party in interest is Abbott Laboratories, Abbott Park, Illinois.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-52 were originally filed in the application. Claims 7, 14, 25, 32, and 43 were cancelled. Claims 1-6, 8-13, 15-24, 26-31, 33-42, and 44-52 remain pending in the application. No claims are allowed. Claims 1-6, 8-13, 15-24, 26-31, 33-42, and 44-52 stand rejected. Claims 1-6, 8-13, 15-24, 26-31, 33-42, and 44-52 are on appeal.

IV. STATUS OF AMENDMENTS

An Amendment Under 37 C.F.R. 1.16 is being submitted with this Brief on Appeal to correct an error in claim 26. This amendment has not yet been entered.

V. SUMMARY OF INVENTION

This invention provides methods and devices for non-invasively measuring at least one parameter of a biological sample, such as, for example, a body part. Examples of such parameters include the presence of a disease condition, progression of a disease state, presence of an analyte, and concentration of an analyte. In these methods and devices, the temperature of the sample is controlled and is caused to vary between preset boundaries. See page 4, line 27 through page 5, line 2 of the specification.

The methods and devices of this invention measure light that is reflected, scattered, absorbed, or emitted by a biological sample from an average sampling depth, d_{av}, that is confined within a region in the sample wherein temperature is controlled. According to the methods of this

invention, the average sampling depth d_{av}, in human tissue is modified by changing the temperature of the tissue. The average sampling depth increases as the temperature is lowered below the body core temperature and decreases when the temperature is raised above the body core temperature. The "body core temperature" means the temperature of the interior of the body remote from the extremities of the body. Rectal temperature and esophageal temperature represent body core temperature. For normal human beings, body core temperature is 37 ± 1 °C. See page 5, lines 3-14 of the specification.

Changing the temperature at the measurement site changes the light penetration depth in tissue and hence d_{av}. See page 5, lines 14-18 of the specification.

An optical measurement is performed on a biological sample at a first temperature. Then, when the optical measurement is repeated at a second temperature, light will penetrate into the biological sample to a depth that is different from the depth to which light penetrated at the first temperature by from about 5% to about 20%. See page 5, lines 19-23 of the specification.

In one aspect, this invention provides a method of measuring at least one parameter of a biological sample, the method comprising the steps of:

(a) setting the temperature of the biological sample to a first temperature, the first temperature being within the physiological temperature range of the biological sample;

(b) performing an optical measurement on the biological sample at the first temperature;

(c) determining at least one optical parameter of the biological sample at the first temperature, the first temperature corresponding to a first depth in the biological sample;

(d) changing the first temperature of the biological sample to at least a second temperature, the at least second temperature being within the physiological temperature range of the biological sample;

(e) performing an optical measurement on the biological sample at the at least second temperature;

(f) determining at least one optical parameter of the biological sample at the at least second temperature, the at least second temperature corresponding to a second depth in the biological sample; and

(g) determining the at least one parameter of the biological sample from the functional dependence of the at least one optical parameter on depth in the biological sample.

See page 6, lines 3-24 of the specification.

Parameters of biological samples include, but are not limited to, the presence of a disease condition, the progression of a disease state, the presence of an analyte, or the concentration of an analyte. See page 6, lines 26-28 of the specification.

In another aspect, the present invention provides a method of measuring at least one parameter of a biological sample having a plurality of layers. In this method, the first layer is located at a first depth of the biological sample, and the at least second layer is located at at least a second depth of the biological sample. See page 7, lines 1-24 of the specification.

The method of this invention can be used to determine a disease state or screen a population of individuals for a disease state. See page 7, lines 26-27 of the specification.

In the preferred embodiments, radiation, i.e., light, is introduced into the surface of a biological sample, such as a body part, at a light introduction site. The diffusely reflected light collected at one or more light collection sites located on the surface of the sample at different distances, r, from the light introduction site is measured. For a given light collection site at a specific distance r from the light introduction site (sampling distance), the average light penetration depth in the biological sample varies with temperature. Light penetrates deeper into the biological sample as temperature is lowered below the body core temperature. See page 7, line 28 through page 8, line 5 of the specification.

This invention involves increasing the penetration depth of radiation, i.e., light, into a biological sample by decreasing the temperature of the biological sample below the body core temperature (37±1 °C), while keeping the wavelength and the separation between the light introduction site and the light collection site (sampling distance) constant. See page 8, lines 6-14 of the specification.

In another aspect, this invention provides an apparatus for determination of at least one parameter of a biological sample. The apparatus 10 comprises:

(a) a means 26 for irradiating a region of the biological sample with light;

(b) a means 28, 30, 32, 34, 36, and 38 for collecting light re-emitted from the region of the biological sample,

(c) a means 40, 42, 44, and 46 for changing the temperature of the biological sample to a temperature within the physiological range of the

biological sample so that radiation penetrates to a specified depth in the biological sample,

(d) a means (not shown) for measuring the intensity of the collected re-emitted light at a plurality of temperatures, wherein the measured intensities correspond to light re-emitted from different depths of the biological sample; and

(e) a means (not shown) for calculating at least one parameter of the biological sample from the dependence of at least one optical parameter on depth in the biological sample.

See page 8, lines 15-29 of the specification.

The method of this invention allows measuring changes in optical properties of a small volume of a biological sample along the light propagation path, perpendicular to the surface of the sample. These changes are measured by using small sampling distances, by controlling the temperature range of the biological sample at the measurement site, and by varying the temperature within the physiological temperature range. The method of this invention is preferable to those methods of the prior art that use large sampling distances. Those methods are silent as to the effect of temperature variation on optical properties pf tissue. The method of this invention avoids the adverse effects of skin surface irregularities and major tissue structural homogeneities, because the method detects only the changes in optical properties at different depths while keeping the sampling distance and wavelengths of light constant. See page 9, lines 3-14 of the specification.

The method of this invention relies on two measurements performed at the same site on the surface of the biological sample, thereby decreasing the effect of repositioning error and the possibility of the optical probe being in contact with different micro-structural regions of the biological sample during different measurements. See page 9, lines 21-26 of the specification.

The change in light penetration depth can be used for diagnosing certain disease states that affect cutaneous structure, cutaneous vascular structure, and cutaneous blood flow. Diabetes, diabetic neuropathy, and peripheral vascular disease are examples of disease states that can be diagnosed by the method of this invention. See page 10, lines 10-15 of the specification.

VI. ISSUES

1. Are claims 1-3, 6-21, 24-39, 42-51 unpatentable under 35 U. S. C. § 103 (a) as being obvious over U. S. Patent No. 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al.?

2. Are claims 4-5, 22-23, and 40-41 unpatentable under 35 U. S. C. § 103 (a) as being obvious over U. S. Patent No. 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. and in view of U. S. Patent No. 5,782,755 to Chance et al.?

3. Is claim 52 unpatentable under 35 U. S. C. § 103 (a) as being obvious over U. S. Patent No. 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. and in view of U. S. Patent No. 5,873,821 to Chance et al.?

4. Are claims 1-3, 8-13, 15-16, 19-21, 26-31, 33-34, 37-39, 44-46, and 49 unpatentable under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 15, 33, 35-36 of U. S. Serial No. 09/080,470 to Khalil et al. in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al.?

VII. GROUPING OF CLAIMS

The claims stand or fall together.

VIII. ARGUMENT

Rejections Under 35 U.S.C. § 103

Claims 1-3, 6-21, 24-39, and 42-51

Mills, U. S. Patent No. 5,978,691 (hereinafter "Mills"), discloses a method for facilitating the noninvasive determination of characteristics of subject matter and the environment in which the subject matter exists. The method comprises the steps of:

emitting at least one wavelength of electromagnetic radiation applied to the subject matter;

detecting said wavelength after contact with the subject matter;

inducing a temperature change in the subject matter while emitting and detecting said radiation applied to the subject matter;

computing parameters based on information processed from the contact of said radiation at various temperature levels on the subject matter.

Laufer et al., "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" (hereinafter "Laufer et al."), discloses the effect of temperature on the optical properties of human dermis and subdermis as a function of near-infrared wavelength between 25 °C and 40 °C. Measurements were performed *ex vivo* on a total of nine skin samples taken from the abdomen of three individuals.

The present invention involves a method comprising the following steps:

(1) the temperature of a biological sample is set to a first temperature and the biological sample is allowed to equilibrate at the first temperature before optical data are collected at the first temperature, the first temperature being within the range of from about 0 °C to about 45 °C;

(2) the first temperature of the biological sample is changed to at least a second temperature and the biological sample is allowed to equilibrate at the at least second temperature before optical data are collected at the at least second temperature, the at least second temperature being within the range of from about 0 °C to about 45 °C.

The first temperature corresponds to a first depth of the biological sample. The at least second temperature corresponds to a second depth of the biological sample.

Mills fails to disclose the requirement of allowing a biological sample to equilibrate at a given temperature before optical data are collected at that temperature. The specification of Mills says nothing about equilibration of a biological sample at a given temperature before optical data are collected at that temperature. Claim 19 of Mills recites that a temperature change is induced in the blood while radiation is emitted and detected through the blood. See column 17, lines 63-64 of Mills. Claim 34 of Mills recites that a temperature change is induced in the subject matter while radiation applied to the subject matter is emitted and detected. See column 19, lines 3-5 of Mills. Thus, it can be seen that Mills teaches away from equilibration of the biological sample at a given temperature prior to the collection of optical data, because equilibration requires a significant delay prior to the collection of optical data.

In the present invention, light at at least one wavelength (e.g., 590 nm, 650 nm, 800 nm) is introduced into a biological sample (e.g., human forearm tissue) at the surface of the biological sample. Light that is reflected, scattered, absorbed, or emitted by the biological sample is measured from an **average sampling depth** (e.g., 0.99 mm to 1.45 mm) that is confined within a temperature-controlled region in the biological sample. The recognition and employment of average sampling depth is a key feature of the present invention. Average sampling depth can be characterized as the average light penetration depth in the biological sample over the range of wavelengths employed in the measurement. As shown in Table 1, page 31 of the specification, the average light penetration depth ranges from 0.72 mm to 2.04 mm over the wavelength range 550 nm to 900 nm. In Mills, the concept of average sampling depth is non-existent. In one embodiment of Mills, the emitted light travels through the entire depth of the biological sample (i.e., a finger). Mills fails to disclose or suggest at what average sampling depth of the biological sample the blood vessels under observation are located. Each temperature used in the method of the present invention corresponds to a particular depth in the biological sample. In another embodiment of Mills, Mills alludes to reflectance. With respect to this embodiment, Mills does not bring up the concept of **average sampling depth** in a biological sample, even in an indirect manner.

The method of this invention requires the use of an intact tissue. Laufer et al. can be used only with excised tissue, for the reason that Laufer et al. requires significant sample preparation (see the first 10 lines of Discussion at page 2484 of Laufer et al.). Thus, Laufer et al. teaches away from the use of a sample of intact tissue. From the foregoing, it is submitted that the combination of Mills and Laufer et al. fails to render the claims on appeal obvious to one of ordinary skill in the art for the following reasons:

(1) The method described in Laufer et al. is used only with excised tissue; the method of this invention requires intact tissue;

(2) Mills performs optical measurements before the samples were allowed to equilibrate at the temperature at which optical data are collected; the method of this invention requires that the samples be allowed to equilibrate at a given temperature before optical data are collected;

(3) Mills discloses nothing relating to the effect of temperature change upon **average sampling depth** that is confined within a temperature controlled region in the body part; the method of this invention relies on the relationship between wavelength of the light used, temperature of the biological sample, and average sampling depth in the biological sample. The following table shows which features are described in Mills and Laufer et al. and claimed in the present application.

	Equilibration	d_{av} in intact tissue
Mills	No	No
Laufer et al.	Yes	No
Present invention	Yes	Yes

The combination of Mills and Laufer et al. results from a piecemeal reconstruction of the prior art. A piecemeal reconstruction of the prior art cannot be a basis for a holding of obviousness. It is impermissible within the framework of 35 U. S. C. § 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to a full appreciation of what such reference fairly suggests to one of ordinary skill in the art. In the situation presented here, equilibration of the sample is chosen from Laufer et al., but the use of excised skin with measurements performed *ex vivo* (as shown in Laufer et al.) is excluded. The use of intact skin is chosen from Mills, but non-equilibration of the sample (as shown in Mills) is excluded. Moreover, Mills even teaches away from equilibration of the sample. Thus, the combination of Mills and Laufer et

al. fails to render the claims on appeal obvious to one of ordinary skill in the art.

Claims 4-5, 22-23, and 40-41

Chance et al., U. S. Patent No. 5,782,755 (hereinafter "Chance '755") discloses a scheme for monitoring one or more solutes in a biological system comprising the steps of:

> delivering light into a biological system containing one or more solutes, the light having a wavelength selected to be in a range wherein at least one of the one or more solutes is substantially non-absorbing;
>
> detecting at least first and second portions of the delivered light, the first portion having traveled through the biological system along one or more paths characterized by a first average path length , and the second portion having traveled through the biological system along one or more paths characterized by a second average path length that is greater than the first average path length; and
>
> comparing the first and second portions of the delivered light to monitor a concentration of one or more of the solutes in the biological system.

Claims 4 and 5 incorporate all of the features of claim 1; claims 22 and 23 incorporate all of the features of claim 19; claims 40 and 41 incorporate all of the features of claim 37. Each of these claims requires intact human tissue; each of these claims requires the biological sample to be equilibrated prior to performance of optical measurements; each of these claims requires the temperature at which the measurement is performed to correspond to a specific depth in the biological sample. Chance et al. '755 fails to remedy the deficiencies of the combination of Mills and Laufer et al. Accordingly, the combination of Chance et al. '755, Mills, and Laufer et al. fails to render claims 4-5, 22-23, and 40-41 obvious to one of ordinary skill in the art.

Claim 52

Chance et al., U. S. Patent No. 5,873,821 (hereinafter "Chance et al. '821"), discloses an oximeter disposed on an endoscope, catheter or guidewire or the like for insertion via a body passage to internal tissue, and including means such as an inflatable balloon to press the oximeter sensor against the localized tissue of interest.

Claim 52 incorporates all of the features of claim 37. This claim requires intact human tissue; this claim requires the temperature at which the measurement is performed to correspond to a specific depth in the biological sample. Chance et al. '821 fails to remedy the deficiencies of the combination of Mills and Laufer et al. Accordingly, the combination of Chance et al. '821, Mills, and Laufer et al. fails to render claim 52 obvious to one of ordinary skill in the art.

Rejection under the judicially created doctrine of obviousness-type double patenting

Appellant will file a Terminal Disclaimer when claims 13, 15, 33, 35-36 U. S. Serial No. 09/080,470 are issued.

CONCLUSION

In view of the foregoing, it is submitted that claims 1-6, 8-13, 15-24, 26-31, 33-42, and 44-52 are in condition for allowance, and it is requested that the Final Rejection be reversed.

APPENDIX OF CLAIMS

The text of the claims on appeal are:

1. A method of measuring at least one parameter of a biological sample, said method comprising the steps of:

(a) setting the temperature of said biological sample to a first temperature and allowing said biological sample to equilibrate at said first temperature before optical data are collected at said first temperature, said first temperature being within the range of from about 0 °C to about 45 °C;

(b) performing an optical measurement on said biological sample at said first temperature;

(c) determining at least one optical parameter of said biological sample at said first temperature, said first temperature corresponding to a first depth in said biological sample;

(d) changing said first temperature of said biological sample to at least a second temperature and allowing said biological sample to equilibrate at at least said second temperature before optical data are collected at said at least said second temperature, said at least second temperature being within the range of from about 0 °C to about 45 °C;

(e) performing said optical measurement on said biological sample at said at least second temperature;

(f) determining said at least one optical parameter of said biological sample at at least a second temperature, said at least second temperature corresponding to a second depth in said biological sample; and

(g) determining said at least one parameter of said biological sample from the functional relationship of said at least one optical parameter on depth in said biological sample, wherein said biological sample comprises intact human tissue.

2. The method of claim 1, wherein said change in temperature of said biological sample results in a change in penetration depth of light in said biological sample.

3. The method of claim 1, wherein said optical measurement is a diffuse reflectance measurement.

4. The method of claim 1, wherein said optical measurement is a spatially resolved diffuse reflectance measurement.

5. The method of claim 1, wherein said optical measurement is a frequency domain measurement.

6. The method of claim 3, wherein said diffuse reflectance measurement is performed at a single sampling distance.

8. The method of claim 1, wherein said first temperature and said at least second temperature are within a range from about 15 °C to about 45 °C.

9. The method of claim 1, wherein said optical measurement is performed using light at at least one wavelength in a range from about 400 nm to about 2500 nm.

10. The method of claim 1, wherein said optical measurement is performed using light at at least one wavelength in a range from about 600 nm to about 1300 nm.

11. The method of claim 1, wherein said at least one parameter of said biological sample is the concentration of an analyte.

12. The method of claim 11, wherein said analyte is glucose, hemoglobin, or water.

13. The method of claim 1, wherein said at least one optical parameter is absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, or light penetration depth.

15. The method of claim 1, wherein said biological sample is a human body part.

16. The method of claim 1, wherein said biological sample is intact human skin, esophagus tissue, intestine tissue, or cervical tissue.

17. The method of claim 1, wherein said at least one parameter of said biological sample is a parameter indicating a disease state.

18. The method of claim 17, wherein said disease state is diabetic state, vascular disease state, dermatological disease state, or neoplasmic disease state.

19. A method of measuring at least one parameter of a biological sample having a plurality of layers, said method comprising the steps of:

(a) setting the temperature of said biological sample to a first temperature and allowing said biological sample to equilibrate at said first temperature before optical data are collected at said first temperature, said first temperature being within the range of from about 0 °C to about 45 °C;

(b) performing an optical measurement on said biological sample at said first temperature;

(c) determining at least one optical parameter of a first layer of said biological sample, said first layer being located at a first depth of said biological sample, said first temperature corresponding to a first depth of said biological sample;

(d) changing said first temperature of said biological sample to at least a second temperature and allowing said biological sample to equilibrate at said at least second temperature before optical data are collected at said at least second temperature, said at least second temperature being within the range of from about 0 °C to about 45 °C;

20. The method of claim 19, wherein said change in temperature of said biological sample results in a change in penetration depth of light in said biological sample.

21. The method of claim 19, wherein said optical measurement is a diffuse reflectance measurement.

22. The method of claim 19, wherein said optical measurement is a spatially resolved diffuse reflectance measurement.

23. The method of claim 19, wherein said optical measurement is a frequency domain measurement.

24. The method of claim 21, wherein said diffuse reflectance measurement is performed at a single sampling distance.

26. The method of claim 19, wherein said first temperature and said at least second temperature are within a range from about 15 °C to about 42 °C.

27. The method of claim 19, wherein said optical measurement is performed using light at at least one wavelength in a range from about 400 nm to about 2500 nm.

28. The method of claim 19, wherein said optical measurement is performed using light at at least one wavelength in a range from about 600 nm to about 1300 nm.

29. The method of claim 19, wherein said at least one parameter of said biological sample is the concentration of an analyte.

30. The method of claim 29, wherein said analyte is glucose, hemoglobin, or water.

31. The method of claim 19, wherein said at least one optical parameter is absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, or light penetration depth.

33. The method of claim 19, wherein said biological sample is a human body part.

34. The method of claim 19, wherein said biological sample is intact human skin, esophagus tissue, intestine tissue, or cervical tissue.

35. The method of claim 19, wherein said at least one parameter of said biological sample is a parameter indicating a disease state.

36. The method of claim 35, wherein said disease state is diabetic state, vascular disease state, dermatological disease state, or neoplasmic disease state.

37. An apparatus for measuring at least one optical parameter of a biological sample, said apparatus comprising:

(a) a means for irradiating a region of said biological sample with light;

(b) a means for collecting light re-emitted from said region of said biological sample;

(c) a means for changing the temperature of said biological sample to a temperature ranging from about 0 °C to about 45 °C so that radiation penetrates to a specified depth in said biological sample,

(d) a means for measuring the intensity of the collected re-emitted light at a plurality of temperatures, wherein the measured intensities correspond to light re-emitted from different depths of said biological sample; and

(e) a means for calculating at least one parameter of said biological sample from the dependence of at least one optical parameter on depth in said biological sample, wherein said biological sample comprises intact human tissue.

38. The apparatus of claim 37, wherein said change in temperature of said biological sample results in a change in penetration depth of light in said biological sample.

39. The apparatus of claim 37, wherein said intensity of said collected re-emitted light is used to determine diffuse reflectance of said biological sample.

40. The apparatus of claim 37, wherein said intensity of said collected re-emitted light is used to determine spatially resolved diffuse reflectance of said biological sample.

41. The apparatus of claim 37, wherein said intensity of said collected re-emitted light is used to determine a frequency domain measurement of said biological sample.

42. The apparatus of claim 37, wherein said intensity of said collected re-emitted light is determined at a single sampling distance.

44. The apparatus of claim 37, wherein said light used to irradiate said sample has at least one wavelength ranging from about 400 nm to about 2500 nm.

45. The apparatus of claim 37, wherein said light used to irradiate said sample has at least one wavelength ranging from about 600 nm to about 1300 nm.

46. The apparatus of claim 37, wherein said at least one parameter of said biological sample is the concentration of an analyte.

47. The method of claim 46, wherein said analyte is selected from the group consisting of glucose, hemoglobin, and water.

48. The apparatus of claim 37, wherein said at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, or light penetration depth.

49. The apparatus of claim 37, wherein said biological sample is selected from the group consisting of intact human skin, esophageal tissue, intestine tissue, or cervical tissue.

50. The apparatus of claim 37, wherein said at least one parameter of said biological sample is an indicator of a disease state.

51. The apparatus of claim 37, wherein said at least one optical parameter is indicative of a disease state, wherein said disease state is selected from the group consisting of diabetic state, vascular disease state, dermatological disease state, and neoplasmic disease state.

52. The apparatus of claim 37, wherein said irradiation means and said temperature changing means are included in an endoscope.

Respectfully submitted,
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